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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,831	09/24/2003	Gerald F. Sigler	RDID 01034CIP US	6994
23690 7590 12/22/2006 Roche Diagnostics OPERATIONS Inc. 9115 Hague Road PO Box 50457 Indianapolis, IN 46250-0457			EXAMINER CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/669,831	Applicant(s) SIGLER ET AL.	
	Examiner Mary (Molly) E. Ceperley	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,21,22,31,33-37,48,49,52,54,56,59,66,81 and 82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,21,22,31,33-37,48,49,52,54,56,59,66,81 and 82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/>Paper No(s)/Mail Date _____</p> | <p>4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. <u>12/14/06</u></p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|---|

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**1)** The request for change of inventorship to delete Richard Terry Root as an inventor has not been approved for the reason that the <sup>to</sup>fee<sub>1</sub> their deposit charge account as required under 37 CFR 1.17(i) has not been authorized by applicants.

**2)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**3)** Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing and indefinite. Since "m" is defined as "0" and "L" is defined as "0 carbon atoms", these two groups are, in essence, not present in the claimed structure; since "m" is "0", "Y" is also not present in the structure. It is unclear why these groups remain as defined variables.

**4)** Claims 1 and 3 are again rejected under 35 U.S.C. 112, first paragraph, for the reason stated in paragraph **6)** of the May 08, 2006 Office action. See paragraph **3)** above. There is no enablement in the specification for the preparation of the compound of claim 1 where the linker "L" is absent {as required by the definition of "L"}.

**5)** Claims 1, 3, 21, 22, 31, 33-37, 48, 49, 52, 54, 56, 59, 66, 81 and 82 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **a)** the admitted prior art as set forth in the specification taken in combination with Vierling et al {FR 98 00728} and optionally with **b)** Bieniarz et al {US 5,380,873} for the reason set forth in paragraph **10)** of the May 08, 2006 Office action.

Applicants' arguments filed November 01, 2006 have been fully considered but they are not persuasive. Applicants argue that since Vierling is directed to the production of pro-drugs, which by their very nature are degradable to the original drug, the skilled artisan would not be motivated to make stable

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derivatives based on the reaction of the hydroxy functional group of the Vierling compound. This argument is considered to be unpersuasive however, for the reason that the Vierling reference has been applied for its description of the hydroxy group as being the reactive functional group for a series of structurally related HIV protease inhibitors. Since this hydroxy group is clearly the reactive group of the compound, it would logically be the location for the reaction to attach a linker-activated ester group to the known drug molecule according to the conventional methods of the art {see the linker-activated ester groups of Bieniarz et al}. The fact that different groups attached to the hydroxy function in the Vierling compounds might hydrolyze *in vivo*, does not negate the fact that the hydroxy function would be expected to be the reactive group appropriate for conjugation of a linker-activated ester as described by the admitted prior art and Bieniarz et al. The motivation to combine the cited references is described in the last subparagraph of paragraph **10)** of the May 08, 2006 Office action.

**6)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

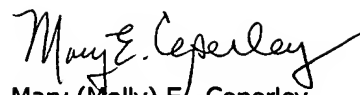
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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December 14, 2006

  
Mary (Molly) E. Ceperley  
Primary Examiner  
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